

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MALLINCKRODT PLC,
MALLINCKRODT PHARMACEUTICALS
IRELAND LIMITED, MALLINCKRODT
HOSPITAL PRODUCTS IP UNLIMITED
COMPANY, and INO THERAPEUTICS
LLC,

Plaintiffs,

v.

AIRGAS THERAPEUTICS LLC, AIRGAS
USA LLC, and AIR LIQUIDE S.A.,

Defendants.

Civil Action No. 22-1648-RGA

MEMORANDUM ORDER

Before me is Defendant Air Liquide S.A.’s motion to dismiss the Complaint¹ against it for lack of personal jurisdiction and for failing to state a claim upon which relief can be granted. (D.I. 37). I have considered the parties’ briefing. (D.I. 38, 59, 108). For the reasons set forth below, I will GRANT the motion to dismiss.

I. BACKGROUND

On December 30, 2022, Plaintiffs sued Defendants for patent infringement related to Abbreviated New Drug Application No. 203144, which seeks approval to market a generic

¹ Plaintiffs amended the Complaint after the present motion was fully briefed. (D.I. 173). The parties filed a joint stipulation stating that the Amended Complaint “contains no new allegations and claims against ALSA beyond those included in the Complaint.” (D.I. 171 at 2). The parties therefore agree that the present motion does not need supplementation. (*Id.*). The parties further agree, “To the extent that the Court grants or denies the Motion to Dismiss, this decision will apply equally to the Proposed Amended Complaint.” (*Id.* at 3). I therefore consider the original Complaint for the purpose of this motion.

version of Plaintiffs' INOmax therapy. (D.I. 1 ¶ 1). Defendants Airgas Therapeutics LLC and Airgas USA LLC are incorporated in Delaware. (*Id.* ¶¶ 4, 7; D.I. 11 ¶¶ 4, 7). Defendant Air Liquide S.A. ("ALSA") is a French company. (D.I. 1 ¶ 10; D.I. 38 at 1).

The Complaint alleges that Airgas Therapeutics LLC is a wholly-owned subsidiary of Airgas USA LLC. (D.I. 1 ¶ 7). ALSA contends that Airgas USA LLC and Airgas Therapeutics LLC are wholly-owned subsidiaries of Airgas, Inc. (D.I. 39 ¶ 3). The Complaint also alleges that Airgas USA LLC and Airgas Therapeutics LLC are wholly-owned subsidiaries of ALSA. (D.I. 1 ¶ 10). ALSA, however, contends it "is separated by at least five degrees of corporate structure from the other two defendants in this matter." (D.I. 39 ¶ 3).

On March 3, 2023, Defendants Airgas Therapeutics LLC and Airgas USA LLC filed an answer. (D.I. 11). ALSA thereafter filed the present motion, asserting a lack of personal jurisdiction over it. (D.I. 37).

II. LEGAL STANDARDS

A. Personal Jurisdiction

Pursuant to Federal Rule of Civil Procedure 12(b)(2), a party may move to dismiss a case based on the court's lack of personal jurisdiction over that party. Because all claims in this suit are for patent infringement, Federal Circuit law controls the personal jurisdiction analysis. *See Pennington Seed, Inc. v. Produce Exch. No. 299*, 457 F.3d 1334, 1343 (Fed. Cir. 2006). Under Federal Circuit law,

where the district court's disposition as to the personal jurisdictional question is based on affidavits and other written materials in the absence of an evidentiary hearing, a plaintiff need only to make a prima facie showing that defendants are subject to personal jurisdiction. In the procedural posture of a motion to dismiss, a district court must accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits in the plaintiff's favor.

Elecs. for Imaging, Inc. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003) (citations omitted).

For claims arising under federal law, if a defendant is not subject to jurisdiction in any state's courts of general jurisdiction, a federal court may have jurisdiction if the constitutional requirements for due process are satisfied with respect to the United States as a whole under Federal Rule of Civil Procedure 4(k)(2).

Rule 4(k)(2) allows a court to exercise personal jurisdiction over a defendant if (1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process. The third requirement under Rule 4(k)(2)—the due process analysis—contemplates a defendant's contacts with the entire United States, as opposed to the state in which the district court sits.

M-I Drilling Fluids UK Ltd. v. Dynamic Air Ltda., 890 F.3d 995, 999 (Fed. Cir. 2018) (cleaned up).

A plaintiff may also request jurisdictional discovery. “If a plaintiff presents factual allegations that suggest ‘with reasonable particularity’ the possible existence of the requisite ‘contacts between [the party] and the forum state,’ the plaintiff’s right to conduct jurisdictional discovery should be sustained.” *Toys “R” Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003) (citation omitted).

B. Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a complainant to provide “a short and plain statement of the claim showing that the pleader is entitled to relief” Federal Rule of Civil Procedure 12(b)(6) allows the accused party to bring a motion to dismiss the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations “could not raise a claim of entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

III. DISCUSSION

A. Personal Jurisdiction

Plaintiffs contend that this Court has jurisdiction over ALSA under Federal Rule of Civil Procedure 4(k)(2). (*See* D.I. 1 ¶ 27).

ALSA argues that Plaintiffs’ allegations do not establish personal jurisdiction over it. (D.I. 38 at 13). ALSA contends, “[T]he Complaint only makes the conclusory allegation that jurisdiction is proper based on ALSA’s alleged ‘submitting various ANDAs to the FDA, and manufacturing, selling, and/or distributing medical gases and/or equipment throughout the United States.’” (*Id.* (quoting D.I. 1 ¶ 27)). ALSA argues this allegation lacks factual support. (*Id.*).²

Plaintiffs disagree. First, they argue that ALSA purposefully directs its activities at U.S. residents. (D.I. 59 at 10). Plaintiffs contend that: (1) ALSA’s statements on its website indicate that it purposefully directs its activities at the United States (*id.* (citing D.I. 60-2 at 57–58 of 127)); (2) the Complaint pleads an agency relationship between ALSA and the other Defendants (*id.* at 10–13 (citing D.I. 1 ¶¶ 12, 15; D.I. 39 ¶ 12; D.I. 60-1 at 10, 12, 15 of 129 (Exhibit 3); *id.* at 21 of 129 (Exhibit 4); *id.* at 49 of 129 (Exhibit 5); *id.* at 58–60 of 129 (Exhibit 7); *id.* at 113 of 129 (Exhibit 8))); and (3) ALSA “directed regulatory activities for the accused ANDA in the United States” and “works actively to grow its U.S. presence” (*id.* at 13 (citing D.I. 60-1 at 2 of 129 (Exhibit 1); D.I. 60-2 at 72–74 of 127 (Exhibit 13))).

² Although ALSA makes additional arguments about general and specific jurisdiction with references to Delaware’s long-arm statute, ALSA acknowledges, “Plaintiffs do not allege that ALSA is subject to general or specific jurisdiction in Delaware.” (D.I. 38 at 8–12). Plaintiffs respond, “Jurisdiction over ALSA is predicated on Rule 4(k)(2), the federal long-arm over foreign defendants, as alleged in the [C]omplaint.” (D.I. 59 at 8). I therefore only consider Rule 4(k)(2).

Second, Plaintiffs argue that ALSA’s “involvement in the development, submission, and eventual marketing of the ANDA and ANDA product confers jurisdiction.” (*Id.* at 14).

Plaintiffs contend that Air Liquide Healthcare America Corporation, a subsidiary of ALSA, filed the ANDA more than ten years ago. (*Id.*). ALSA, Plaintiffs contend, audited the “identified manufacturing facility.” (*Id.*). Plaintiffs argue, “ALSA was also responsible for transferring the ANDA away from Air Liquide Healthcare America Corporation in 2018.” (*Id.*). Plaintiffs further argue ALSA remains involved with the ANDA, as ALSA “sought to acquire [Plaintiffs’] business, including the contracts with hospitals, right on the eve of when the ANDA was approved by FDA.” (*Id.* at 15).

Third, Plaintiffs argue that jurisdiction over ALSA is fair and reasonable. (*Id.*). Plaintiffs contend that ALSA waived any arguments about reasonableness because it “d[id] not even attempt to address any [*Burger King*] factors.” (*Id.*). Plaintiffs argue that each factor supports its position: (1) “there is minimal burden in requiring ALSA to appear in the United States”; (2) “the United States has an interest in enforcing its patent laws”; (3) Plaintiffs have “an interest in obtaining effective and convenient relief”; (4) “it serves the judicial system to resolve this case in a single forum under a single set of rules”; and (5) “the United States is served by the perception of fairness arising from a system in which a foreign entity should expect to face lawsuits in the U.S. for its infringing conduct in the country.” (*Id.* at 16).

In its reply, ALSA argues Plaintiffs incorrectly infer that any references to the Air Liquide group are references to ALSA. (D.I. 108 at 1). ALSA also contends that Plaintiffs have failed to establish an agency relationship between ALSA and the other Defendants. (*Id.* at 8).

For the purpose of this analysis, the parties do not dispute that the claim arises under federal law, nor that ALSA is not subject to jurisdiction in any state’s courts of general

jurisdiction. This leaves the issue of whether exercising jurisdiction is consistent with the Constitution. (*See* D.I. 59 at 9; D.I. 108 at 2).

This step looks to whether a defendant’s “contacts with the United States, but not with the forum state, satisfy due process.” *M-I Drilling Fluids*, 890 F.3d at 999 (quoting *Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico*, 563 F.3d 1285, 1296 (Fed. Cir. 2009)). “[D]ue process requires only that in order to subject a defendant to a judgment in personam, [the defendant must] have certain minimum contacts with [the forum] such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice.’” *Synthes*, 563 F.3d at 1296 (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). “Relevant to that determination, [courts] apply a three-part test considering whether: (1) the defendant purposefully directed its activities at residents of the forum; (2) the claim arises out of or relates to the defendant’s activities with the forum; and (3) assertion of personal jurisdiction is reasonable and fair.” *M-I Drilling Fluids*, 890 F.3d at 1000.

“The plaintiff bears the burden as to the first two requirements, and if proven, the burden then shifts to the defendant to ‘present a compelling case that the presence of some other considerations would render jurisdiction unreasonable.’” *Id.* (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985)). The reasonableness analysis for Rule 4(k)(2) considers the five *Burger King* factors: “(1) the burden on the defendant; (2) the forum’s interest in adjudicating the dispute; (3) the plaintiff’s interest in obtaining convenient and effective relief; (4) the interstate judicial system’s interest in obtaining the most efficient resolution of controversies; and (5) the shared interest of the states in furthering fundamental substantive social policies.” *Id.* at 1002 (citing *Burger King*, 471 U.S. at 477).

I do not think that Plaintiffs have met their burden of pleading that ALSA purposefully directs its activities at U.S. residents. As ALSA's declaration indicates, the group of Air Liquide companies includes various entities other than ALSA, Airgas Therapeutics LLC, and Airgas USA LLC. (D.I. 39 ¶ 3).³ The evidence Plaintiffs cite does not suggest that ALSA, rather than another company in the Air Liquide group, has contacts with the United States. Plaintiffs' reference to a website, for example, mentions both "Air Liquide" and "[t]he Group." The website states, "Today, Air Liquide in the U.S. is comprised of two main entities." (D.I. 60-2 at 58 of 127). Given that the website describes the Air Liquide group generally, this evidence does not suggest that ALSA itself has contacts with the United States.

Plaintiffs' allegations about an agency relationship between ALSA and the other Defendants do not support personal jurisdiction either. To determine whether an agency relationship exists, courts examine the following factors: "the extent of overlap of officers and directors, methods of financing, the division of responsibility for day-to-day management, and the process by which each corporation obtains its business." *Applied Biosystems, Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1463 (D. Del. 1991). Plaintiffs rely on *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009), to argue that the allegations in the Complaint are sufficient to plead an agency relationship. Unlike the present case, however, the out-of-state corporation at issue in *Cephalon* purchased more than \$115 million of

³ "ALSA is separated by at least five degrees of corporate structure from the other two defendants in this matter. Airgas Therapeutics LLC and Airgas USA LLC are wholly-owned subsidiaries of Airgas, Inc., which is itself a wholly-owned subsidiary of American Air Liquide Holdings, Inc. (a Delaware corporation). American Air Liquide Holdings, Inc. is owned by American Air Liquide, Inc. (a Delaware company) and Carba Holding AG (a Swiss company). . . . Both American Air Liquide Inc. and Carba Holding AG are wholly-owned subsidiaries of Air Liquide International SA (a French company). ALSA holds virtually all the shares of Air Liquide International SA." (D.I. 39 ¶ 3).

products from a Delaware facility, received consulting services from a Delaware corporation, and contracted with companies located in Delaware, among other activities. *Id.* at 344–45.

Similar facts are absent from Plaintiffs’ pleadings.

Here, both the Complaint (*see* D.I. 1 ¶¶ 12, 15) and Plaintiffs’ supporting exhibits are insufficient to meet Plaintiffs’ burden of pleading an agency relationship. Descriptions of Airgas Therapeutics as “an Air Liquide company” and of Airgas as “Air Liquide’s American subsidiary” seem close to the bare minimum of what would be expected between any parent and subsidiary. (*See* D.I. 60-1 at 58, 113 of 129). Statements that “[t]he Group also has businesses in the United States” and that the acquisition of Airgas “was complementary to the Group’s businesses in the United States and enabled Air Liquide to be present across all market segments both upstream of and downstream to the US market” do not suggest that ALSA is involved in the day-to-day management of the other Defendants. (*See id.* at 10, 12 of 129). Other cited statements—that Airgas “employs nearly 18,000 associates within Air Liquide’s global workforce of 64,500 employees” and that “[t]he Group is organized and based on a consistent Group strategy” (*see id.* at 15, 49 of 129)—likewise do not indicate that ALSA has substantial authority over the other Defendants. *See Nespresso USA, Inc. v. Ethical Coffee Co.*, 263 F. Supp. 3d 498, 505 (D. Del. 2017) (“Nestlé setting the corporate policies and procedures for all subsidiaries is not sufficient evidence of agency.”). Overlap of a few individuals between the non-ALSA Defendants’ management and the Air Liquide group’s management does not disturb that conclusion. *See id.* (“Although two individuals from Nespresso SA share a leadership role with Nestlé, and one additionally holds a leadership position with Nestec, the court has previously found such a tenuous connection to be a ‘minor overlap,’ which is ‘not dispositive’ for finding agency.” (citations omitted)).

I also do not think that Plaintiffs’ references to ANDA documents support a finding of ALSA purposefully directing its activities at the United States. The cited ANDA document states, “Air Liquide Healthcare parent company had acquired Airgas. As a part of the acquisition, Air Liquide’s parent decided to operate the healthcare business in the United States within Airgas USA LLC.” (D.I. 60-1 at 2 of 129). This does not suggest that ALSA itself directed any regulatory activities in the United States. As ALSA contends, the parent company at issue was American Air Liquide Holdings, Inc., not ALSA. (D.I. 108 at 6–7). Plaintiffs do not plead facts to suggest otherwise. Nor does ALSA’s conduct after Plaintiffs’ filing of the Complaint—an email from the Air Liquide group’s M&A director to Plaintiffs about potential business opportunities and a potential takeover (D.I. 60-2 at 74 of 127)—show that ALSA has sufficient contacts with the United States.

Because Plaintiffs have not met their burden to plead that ALSA purposefully directed its activities at the United States, I do not need to consider whether the claims at issue arise out of or relate to ALSA’s activities in the United States, nor whether assertion of personal jurisdiction is reasonable and fair. I conclude that this Court does not have personal jurisdiction over ALSA under Rule 4(k)(2).

B. Rule 12(b)(6)

Because I conclude that this Court does not have personal jurisdiction over ALSA, I do not need to resolve the parties’ Rule 12(b)(6) dispute. That portion of ALSA’s motion is DISMISSED as moot.

C. Jurisdictional Discovery

Plaintiffs request leave to take jurisdictional discovery and amend their pleadings if ALSA’s motion is granted. (D.I. 59 at 20). Plaintiffs argue that “amendment would supply

details that ALSA purports [are] missing.” (*Id.*). Besides, Plaintiffs contend, “There is no bad faith, dilatory motives, or unfair prejudice here because the case is in its early stage.” (*Id.*). Due to the “overwhelming evidence” supporting personal jurisdiction, Plaintiffs argue that amendment would not be futile. (*Id.*).

In its reply, ALSA argues Plaintiffs have not established “with reasonable particularity the possible existence of the requisite contacts” needed to obtain jurisdictional discovery. (D.I. 108 at 10 (quoting *Genzyme Corp. v. Novartis Gene Therapies, Inc.*, 2023 WL 1965090 (D. Del. Feb. 13, 2023))). ALSA contends that amendment of the pleadings would be futile. (*Id.*).

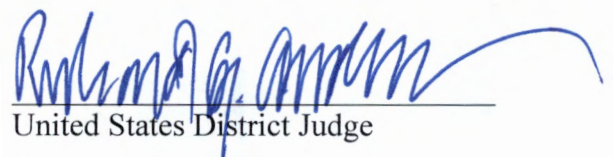
I agree with ALSA. Plaintiffs’ vague assertions about the information they hope to find in jurisdictional discovery—details about “ALSA’s control over the Airgas defendants, contacts with the United States, and involvement in filing and commercializing the ANDA” (D.I. 59 at 20)—place their request in the realm of a “fishing expedition.” *Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). Plaintiffs have not met the “reasonable particularity” standard. *Toys “R” Us*, 318 F.3d at 456.

IV. CONCLUSION

For the reasons discussed above, I GRANT Defendant Air Liquide S.A.’s motion to dismiss the Complaint against it. Dismissal is without prejudice.

IT IS SO ORDERED.

Entered this 22nd day of March, 2024


United States District Judge